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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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BARNES & THORNBURG 11 SOUTH MERIDIAN INDIANAPOLIS, IN 46204			EXAMINER FOSTER, JIMMY G	
			ART UNIT 3728	PAPER NUMBER

DATE MAILED: 06/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/613,144

Applicant(s)

CAVANAGH, MICHAEL SHANE

Examiner

Jimmy G. Foster

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 7/3/03.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

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1) Applicant's "OFFER TO SURRENDER ORIGINAL PATENT GRANT" is objected to as being unsigned.

2) Applicant's reissue declaration filed on 28 November 2003 is objected to under 37 CFR 1.175 (a) as failing to identify the residence and mailing address of the inventor. While the name block underneath the signature of Applicant includes an address, there is no indication that the address is a mailing address or a residence. 37 CFR 1.175 requires a reissue oath or declaration to meet the requirements of 37 CFR 1.63. 37 CFR 1.63(c)(1) requires the identification of the mailing address and identification of the residence if the inventor lives at a different location than that where the inventor customarily receives mail.

The reissue declaration is also objected to under 37 CFR 1.175(a)(1) as failing to state an error in the claims. Applicant has declared that an error was that of claiming more than Applicant had a right to claim. Although the declaration states that failing to cite references led to the error in the claims, the declaration fails to specifically identify at least one error (e.g. by referring to an amendment of a limitation of a claim).

3) Claims 1-12 are rejected under 35 U.S.C 251 as being based upon a defective reissue declaration (defective as described above).

4) Claim 12 is objected to because the wording, "within said instrument recess is position therein" does not make grammatical sense. It appears that "position" should be "positioned".

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5) Claim 12 is considered to patentably distinguish over the prior art, and will be allowable when Applicant files an appropriate supplemental declaration in accordance with 35 CFR 1.175, thereby overcoming the rejection of the claim under 35 U.S.C 251.

6) Claims 1 and 11 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 1 there is no antecedent basis for "the arrangement", making it unclear whether the arrangement is positively recited as structure in the claim, and making it unclear how the arrangement relates to the structural recitation of the recess already set forth in the claim.

In claim 11 there is no antecedent basis for "the arrangement", making unclear whether the arrangement is structure or function in the claim.

7) The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8) Claims 1-6, 10 and 11 are rejected under 35 U.S.C. § 102(b) as being anticipated by Doniger (2,522,213). In the reference of Doniger, there is provided a scalpel at knife 11,13, including a handle/holder 11 and a blade 13 which is attached to the handle. In addition, there is provided a container 10 including a recess (unnumbered) in the base of the container which receives a full scalpel (i.e. handle and blade). This is shown in Figure 1 of the reference.

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Actually, The container base includes multiple recesses for holding multiple scalpels. The recesses are defined between raised elements (unnumbered) in the base. Each recess includes first and second portions. The first portion is portion which holds the blade end and the second portion (on the right) is the portion which holds an end of the handle. Between these portions is defined a wider recess which is inherently capable of being used as finger access recess since this wider recess is shown to be large enough to place one's fingers in order to grasp the handle of a scalpel. Accordingly, this meets Applicant's means-plus-function regarding *access means* (see claim 4), and it meets the finger access recess (set forth in claim 5).

The scalpel 11,13 is substantially shown as having a major dimension, which is the major dimension of the blade or the diameter of the handle. The scalpel is also shown as having a minor dimension, which is the thickness of the blade.

As evident from Figure 1, the major dimension is less than the width of the recess in the base of the container, and the minor dimension (blade thickness) is less than the depth of the recess. Accordingly the blade of the scalpel does not face the opening of the recess, and this inherently prevents a person's fingers from being cut by the blade while in the recess.

The top faces of the raised elements (indicated above), on each flank of a recess portion opening, are apparently shown to be somewhat horizontal. However, these top faces may be considered to define guide means since one can move/guide a scalpel (such as shown), which is intend to be inserted, across one of the top faces toward an adjacent one of the recesses, whereupon registry with the recess will permit the scalpel to enter into the recess. This is not unlike the function claimed for Applicant's guide means since

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Applicant is not claiming any guiding function which would distinguish over guiding in a generally horizontal direction. As with Applicant's guide means 20,21, the movement of the scalpel of Doniger would be across the surface flanking the recess. Accordingly, the top faces of Doniger are considered by the examiner to be equivalents to the subject matter disclosed in Applicant's specification as guide means and as referred to in claim 1 in the means-plus-function, "guide means for guiding a scalpel placed in said container to said scalpel recess".

Regarding the limitation claimed in claim 1, insofar as claimed, which calls for the scalpel blade to be located in one of the (first and second) portions irrespective of the position of the scalpel, this limitation does not distinguish the claimed subject matter over Doniger. This is because the scalpel 11,13 of Doniger may be flipped over, about the longitudinal axis of the scalpel, so as to define another position by which the first recess portion (i.e. the one shown on the left) may receive the blade.

Regarding Applicant's claim 2, which calls for the guide means to be inclined walls which converge to the opening of the recess, this is not considered to distinguish over the side walls of the container base, located at opposite ends of the recess. The top surfaces of the container side walls are inclined, as clearly shown in Figure 1. Since the walls are located immediately adjacent the ends of the recesses, the walls may be said to converge toward the recess openings, insofar as claimed by Applicant.

Regarding claim 3, which calls for the base and side walls of the recess to be radiussed, this does not distinguish over Doniger. The right or second portion of the recess of Doniger, which hold an end of the handle, is shown to be rounded and to therefore include side walls and a base which are radiussed.

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Regarding claim 6, the limitation claiming "barrier means for preventing a user's fingers from entering said scalpel recess" this is not considered to invoke 35 U.S.C 112, 6th paragraph since it recites structure, i.e. "barrier", sufficient for performing the function recited. Moreover, the limitation is not considered to distinguish the claimed subject matter over cover 15 of Doniger since the cover of the reference would prevent access to the recesses in the container base when the cover is closed. Furthermore, even if 35 U.S.C. 112, 6th paragraph were invoked, the function recited in the claim does not distinguish over the function provided by the cover 15 of Doniger since the Doniger cover acts as a barrier to prevent access to the recesses in the base.

Unlike Applicant's claims 1-10, claim 11 does not positively recite its content (the suture holder and needle) as structure but merely as intended use. The suture holder and needle are not introduced in a structural manner in the claim. Moreover, the last paragraph portion of the claim, which refers to "the arrangement", does not overcome this interpretation since there is a lack of antecedent bases for the arrangement, and therefore "arrangement" may be reasonably read as being intended use. Accordingly regarding claim 11, there is no requirement that the prior art include a suture needle and holder. MPEP 2114, explains how intended use/functional language is treated in a product claim.

Further regarding Applicant's claim 11, the container of Doniger includes what appears to be a semi-cylindrical recess (i.e. the recess shown holding the end of the handle/holder 11 of the scalpel/knife. However the recess is inherently capable of receiving a suture needle wherein the point of the needle is pointed downward and therefore away the opening of the

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recess, by which a user's finger is prevented from contacting the point of the needle.

Similarly as stated above, the top faces of the raised elements on each flank of the cylindrical recess portion opening are substantially shown to be somewhat horizontal. However, these top faces may be considered to define guide means since one can move/guide a needle holder with needle across one of the top faces toward the recess, whereupon registry with the recess will permit the appropriately sized and shaped holder with needle to enter into the cylindrical recess recess. This is not unlike the function claimed for Applicant's guide means since Applicant is not claiming any guiding function which would distinguish over guiding in a generally horizontal direction. As with Applicant's guide means 20,21, the movement of the needle holder and needle would be across the surface flanking the recess. Accordingly, the top faces of Doniger are considered by the examiner to be equivalents to the subject matter disclosed in Applicant's specification as guide means and as referred to in claim 11 in the means-plus-function, "guide means for guiding a suturing needle held by a suture holder to said needle recess".

9) Claims 1 and 4-6 are rejected under 35 U.S.C. § 102(b) as being anticipated by the published International Application WO 94/08642 to Ross et al. In the reference of Ross et al there is provided a scalpel 15 (shown in Figs. 2-4) and provided a container at secondary tray 13A which includes a recess (unnumbered) for holding the scalpel.

The recess may be considered to include first and second portions. The first portion is a portion which holds the blade end and the second portion is the portion which holds the handle.

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Beside the recess is defined a wider recess which is inherently capable of being used as finger access recess since this wider recess is shown to be large enough to place one's fingers in order to grasp the handle of a scalpel. Accordingly, this meets Applicant's means-plus-function regarding *access means* (see claim 4), and it meets the finger access recess (set forth in claim 5).

The scalpel 15 is substantially shown as having a major dimension, which is the dimension parallel with the plane of the container. The scalpel is also shown as having a minor dimension, which is the dimension taken vertically and perpendicular to the plane of the container. As evident from Figures 2 and 3, the major dimension is less than the width of the recess, and the minor dimension is less than the depth of the recess. Accordingly the blade of the scalpel does not face the opening of the recess, and this inherently prevents a person's fingers from being cut by the blade while in the recess.

The top planar surface of the container 13A is shown to be somewhat horizontal. However, this top surface may be considered to define guide means since one can move/guide a scalpel (of the type such as shown) across the top surface toward the recess, whereupon registry with the recess will permit the scalpel to enter into the recess. This is not unlike the function claimed for Applicant's guide means since Applicant is not claiming any guiding function which would distinguish over guiding in a generally horizontal direction. As with Applicant's guide means 20,21, the movement of the scalpel of Ross et al would be across the planar surface flanking the recess. Accordingly, the top surface of Ross et al is considered by the examiner to be an equivalent to the subject matter disclosed in Applicant's specification as guide means and as referred to in claim 1 in the means-plus-

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function, "guide means for guiding a scalpel placed in said container to said scalpel recess".

Regarding the limitation claimed in claim 1 which calls for the scalpel blade to be located in one of the (first and second) portions irrespective of the position of the scalpel, this limitation clearly does not distinguish the claimed subject matter over Ross et al. This is because the recess of Ross et al is rectangular, permitting the scalpel 15 in reverse orientation, in which the handle is closer to the corner of the tray.

Regarding claim 6, the limitation claiming "barrier means for preventing a user's fingers from entering said scalpel recess" this is not considered to invoke 35 U.S.C 112, 6th paragraph since it recites structure, i.e. "barrier", sufficient for performing the function recited. Moreover, the limitation is not considered to distinguish the claimed subject matter over label or drape 12 of Ross et al since the label or drape of the reference would prevent access to the recess in the tray 13A as shown in Figure 1. Furthermore, even if 35 U.S.C. 112, 6th paragraph were invoked, the function recited in the claim does not distinguish over the function provided by the label or drape since it acts as a barrier to prevent access to the recesses in the base.

10) Claim 11 is rejected under 35 U.S.C. § 102(b) as being anticipated by Abrams et al (4,917,243). The reference of Abrams et al discloses a container 2, which the reference discloses may be made with an elongated semi-cylindrical shape (see col. 2, lines 25-37). Therefore the recess in the container, which is shaped with as the container, will be semi-cylindrical. Although the reference of Abrams is intended to be for the

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disposal of the needle from a hypodermic syringe, the recess is inherently capable of receiving the end of a suture needle holder with a needle therein instead.

In addition, there is provided a guide means, which may either be the top surface of container 2, or the slit at 3 or the slit at 4, or the slot at 5. This guide means is disclosed for guiding a syringe and needle into the recess so as to avoid accidental pinprick from a used needle; however, this guide means is capable of allowing, instead, the end of an appropriate sized and shaped suture needle holder, with suture needle, to move along its surface into the recess. Accordingly, the guide means is equivalent to Applicant's disclosed guide means with respect to the function claimed by Applicant.

11) The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12) Claim 7 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Doniger (2,522,213) in view of Kiyoshi (5,348,152). The reference of Kiyoshi et al at 5 suggests that the recess for a sharp instrument (e.g. a spare blade) may be provided with reduced width opening (5) which functions so as to retain the instrument in the recess. Accordingly, for this reason it would have been obvious in view of Kiyoshi to have made the recess openings

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for the scalpel 11,13 in the container base of Doniger, as reduced openings for the purpose of retaining the scalpel in the recess. The examiner asserts that such a reduced opening, especially if it engaged with the sides scalpel, as is taught by Kiyoshi for spare blades, would inherently prevent entry by a users fingers into the recess opening.

13) Claim 7 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Ross et al (WO 94/08642) in view of Kiyoshi (5,348,152). The reference of Kiyoshi et al at 5 suggests that the recess for a sharp instrument (e.g. a spare blade) may be provided with reduced width opening (5) which functions so as to retain the instrument in the recess. Accordingly, for this reason it would have been obvious in view of Kiyoshi to have made the recess opening for the scalpel 15 of Ross et al as reduced opening for the purpose of retaining the scalpel in the recess. The examiner asserts that such a reduced opening, especially if it engaged with the sides scalpel, as is taught by Kiyoshi for spare blades, would inherently prevent entry by a users fingers into the recess opening.

14) Claims 8 and 9 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Doniger (2,522,213) in view of Mercier (5,363,862). The reference of Mercier, at 11,20 and especially the embodiment of Figures 8 and 9 wherein a sharp instrument holder/tray (37) is detachably attached to a handle (11), suggests detachably attaching a handle to a holder for sharp instruments for the purpose of protecting a person from injury from the sharp instruments as the as the holder is passed from one place to another.

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Accordingly, it would have been obvious in view of this teaching to have provided the container of Doniger with a detachable handle.

15) Claims 8 and 9 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Ross et al (WO 94/08642) in view of Mercier (5,363,862). The reference of Mercier, at 11,20 and especially the embodiment of Figures 8 and 9 wherein a sharp instrument holder/tray (37) is detachably attached to a handle (11), suggests detachably attaching a handle to a holder for sharp instruments for the purpose of protecting a person from injury from the sharp instruments as the holder is passed from one place to another. Accordingly, it would have been obvious in view of this teaching to have provided the container 13,13A of Ross et al with a detachable handle.

16) Claim 10 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Ross et al (WO 94/08642). since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8. Although the reference of Ross et al only provides one recess in the tray for holding a scalpel 15, it would have been obvious as being a mere duplicate of structure and function to have provided more than one recess which holds more than one scalpel.

17) Applicant is reminded of the continuing obligation under 37 CFR 1.178(b), to timely apprise the Office of any prior or concurrent proceeding in which Patent No. 6,065,596 is or was involved. These proceedings would include interferences, reissues, reexaminations, and litigation.

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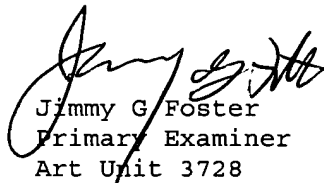
Applicant is further reminded of the continuing obligation under 37 CFR 1.56, to timely apprise the Office of any information which is material to patentability of the claims under consideration in this reissue application.

These obligations rest with each individual associated with the filing and prosecution of this application for reissue. See also MPEP §§ 1404, 1442.01 and 1442.04.

18) Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jimmy G Foster whose telephone number is (571) 272-4554. The examiner can normally be reached on Mon-Fri, 8:45 am - 5:15 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mickey Yu can be reached on (571) 272-4562. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1148.


Jimmy G Foster
Primary Examiner
Art Unit 3728

JGF
15 June 2005